

2 5 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 558-1500

Contact: Kam H. Leung, Ph.D.
(800) 421-0837 x 5386

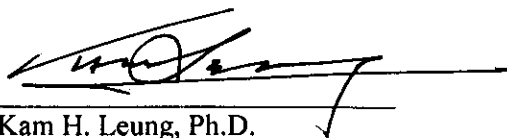
Device Identification: Remote Control
SCB/ValleyLab Force FX Control

Indication: The Storz Communication Bus/ValleyLabs Force FX Control is an interface control box between the SCB computer and the electrosurgical generator. It contains software to display ValleyLab Force FX electrosurgical generator's control parameters on a SCB computer and screen. The Interface Unit serves as a connector box from the Force FX unit to the SCB compatible computer. The unit's software does not perform calculations. It only relays Force FX functions and controls on the SCB monitor for the surgeon's convenient control.

Device Description: The Karl Storz SCB/ValleyLab Force FX Control connects a Storz Communication Bus computer to the ValleyLab Force FX electrosurgical generator. It enables the SCB computer to display and control the FX's functions.

Substantial Equivalence: The Karl Storz SCB/ValleyLab Force FX Interface Unit is substantially equivalent to the predicate device since the basic features and intended uses are the same. The minor differences between the Karl Storz SCB-ValleyLabs Force FX Interface Unit and the predicate device raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed:



Kam H. Leung, Ph.D.
Senior Regulatory Specialist.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2004

Ms. Susie S. Chen
Director, Regulatory Affairs
Karl Storz Endoscopy – America, Inc.
600 Corporate Point 5th Floor
CULVER CITY CA 90230-7600

Re: K041912
Trade/Device Name: SCB/ValleyLab FX Interface Unit
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 KOG
Dated: September 27, 2004
Received: September 30, 2004

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K041912

Device Name: **SCB/ValleyLabs Force FX Interface Unit**

NON-STERILE REUSABLE COMPONENT

NON-STERILE, THE INTERFACE UNIT MUST BE COVERED WITH A STERILE COVER BEFORE USE

INTENDED USE: The Storz Communication Bus/ValleyLabs Force FX Control is an interface control box between the SCB computer and the electrosurgical generator. It contains software to display ValleyLab Force FX electrosurgical generator's control parameters on a SCB computer and screen. The Interface Unit serves as a connector box from the Force FX unit to the SCB compatible computer. The unit's software does not perform calculations. It only relays Force FX functions and controls on the SCB monitor for the surgeon's convenient control.

STORZ

Karl Storz Endoscopy

Karl Storz	600 Corporate Pointe	Phone 310 558 1500
Endoscopy-America, Inc.	Culver City, CA 90230-7600	Toll Free 800 421 0837

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogan
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K041912

Prescription Use ☒

OR

Over-The-Counter Use _____
(Per 21 C.F.R. 801.109)